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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,742	07/19/2006	Brett Finlay	27112-14589	2851

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,742	FINLAY ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-85 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1,4,5,6,7, 21-48 and 74 drawn to a composition comprising a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84, or a fragment or variant thereof, in combination with a physiologically acceptable carrier and a recombinant polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84.

Group II, claim(s) 2, 3, 6, 7, 21-48 , 75-81 and 83-84 drawn to a composition comprising a nucleic acid molecule encoding a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84, or a fragment or variant thereof, in combination with a physiologically acceptable carrier and an isolated nucleic acid molecule comprising a nucleotide sequence substantially identical to the sequence of SEQ ID NOs: 1-21 or 60-72 and a kit comprising a reagent for detecting an A/E pathogen in a sample and a package insert with instructions for detecting the A/E pathogen in the sample, wherein the reagent comprises a probe or primer probe or primer substantially identical to: a) a nucleotide sequence selected from the group consisting of one or more of SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof, or b) a nucleotide sequence encoding a polypeptide substantially identical to one or more of SEQ ID NO: 22-43, 59, 73-84 or a fragment or variant thereof.

Group III, claim(s) 8-48, drawn to a bacterium, or a preparation thereof, wherein the bacterium comprises a mutation in the bacterial genome in a nucleotide sequence that is substantially identical to SEQ ID NOs: 1-21 or 60-72.

Group IV, claim(s) 49-51 and 71-73, drawn to a method of detecting the presence of an A/E pathogen in a sample, the method comprising: a) providing a sample; and b) detecting the presence of a nucleic acid molecule comprising a nucleotide sequence substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof, c) detecting the presence of a nucleic acid molecule encoding a polypeptide substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

Group V, claim(s) 49, 50, 52 and 71-73 drawn to a method of detecting the presence of an A/E pathogen in a sample, the method comprising: detecting the presence of a polypeptide comprising an amino acid sequence substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

Group VI, claim(s) 53-58 and 71-73 drawn to a method for eliciting an immune response against an A/E pathogen, or component thereof, in an animal comprising administering to the animal an effective amount of the composition of any one of claims 1-7 thereby eliciting an immune response in the animal.

Group VII, claim(s) 53-58 and 71-73 drawn to a method for eliciting an immune response against an A/E pathogen, or component thereof, in an animal comprising administering to the animal an effective amount of the composition of any one of 15-48, or comprising administering to the animal an effective amount of the bacterium of any one of claims 8-14, thereby eliciting an immune response in the animal.

Group VIII, claim(s) 59-61 and 71-73, drawn to a method of treating or preventing infection by an A/E pathogen, the method comprising: a) identifying an animal having, or at risk for, an A/E pathogen infection; and b) administering to the animal an effective amount of a compound that attenuates the virulence of an A/E pathogen, wherein the compound inhibits the expression, secretion, or biological activity of a polypeptide comprising an amino acid sequence substantially identical to the sequence of any one of SEQ ID NOs: 22-43, 59, 73-84.

Group IX, claim(s) 62 and 71-73, drawn to a method of attenuating the virulence of an A/E pathogen, the method comprising mutating one or more of a gene selected from the group consisting of nleA, nleB, nleC, nleD, nleE, nleF, nleG, and nleH, or a homologue thereof in the A/E pathogen, or mutating one or more of a nucleotide sequence in the genome of the A/E pathogen, wherein the nucleotide sequence is selected from SEQ ID NOs: 1-21 or 60-72, thereby attenuating virulence.

Group X, claim(s) 63-66 and 71-73, drawn to a method of screening for a compound that attenuates the virulence of an A/E pathogen, the method comprising: a) providing a system comprising: (i) a nucleic acid molecule comprising a nucleotide sequence substantially identical to SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof; or (ii) a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof b) providing a test compound and c) determining whether the test compound modulates the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule, wherein a change in the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule indicates a compound that attenuates the virulence of an A/E pathogen..

Group XI, claim(s) 63-66 and 71-73, drawn to a method of screening for a compound that attenuates the virulence of an A/E pathogen, the method comprising: a) providing a system comprising: a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof; b) providing a test compound; and c) determining whether the test compound modulates the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule, wherein a change in the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule indicates a compound that attenuates the virulence of an A/E pathogen..

Group XII, claim(s) 67-73, drawn to a method of producing a A/E pathogen polypeptide comprising: a) providing a recombinant cell comprising: (i) a nucleic acid molecule comprising a nucleotide sequence substantially identical to SEQ ID NOs: 1-21 or 60-72; or (ii) a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, or 73-84; and b) growing the recombinant cell under conditions that permit expression of the polypeptide.

Group XIII, claim(s) 82, drawn to use of the composition of any one of claims 1-7 or 15-48, the bacterium of any one of claims 8-14, the polypeptide of claim 74, or the nucleic acid molecule of claim 75, for the preparation of a medicament for eliciting an immune response against an A/E pathogen, or component thereof, or for reducing shedding or colonization of an A/E pathogen in an animal, or for treating or preventing infection by an A/E pathogen.

Group XIV, claim(s) 83 and 85, drawn to a kit comprising a reagent for detecting an A/E pathogen in a sample and a package insert with instructions for detecting the A/E pathogen in the sample wherein the reagent comprises an antibody that specifically binds a sequence selected from the group consisting of one or more of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature linking the inventions are the antigens nleA, nleB, nleC, nleD, nleE, nleF, nleG, nleH or Z2076, Z2149, Z2150, Z2151, Z2337, Z2338, Z2339, Z2560, Z2976, or L0043. These antigens lack a common structure *and* function and thus the inventions as a whole lack unity.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species listed above do not

relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species of antigens nleA, nleB, nleC, nleD, nleE, nleF, nleG, nleH or Z2076, Z2149, Z2150, Z2151, Z2337, Z2338, Z2339, Z2560, Z2976, or L0043 lack a common structure *and* function and thus lack unity.

For the invention elected please elect a species of bacterial antigen from SEQ ID NO: 22-43,59 or 73-84 and the variant(s) that read on the elected species. For example if SEQ ID NO: 22 (NleA) is elected in addition identify the variants of NleA including from other bacteria that read on the elected antigen and is listed among SEQ ID NO: 22-43,59 or 73-84. See for example in the drawings NleA from *Citrobacter rodentium* (SEQ ID NO: 22), Enterophathogenic *E.coli* SEQ ID NO: 23 and Enterohemorrhagic E.coli NLeA SEQ ID NO: 24.

Please also identify the nucleic acid that reads on the elected antigen and the variants thereof.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645